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I. STATUS OF CLAIMS

Claims 1, 2-34, and 66-71 are currently pending.

The drawings stand objected under 37 CFR §1.121(d). *See Office Action*, p. 2 (14 Oct 2009).

The specification stands objected for containing an embedded hyperlink and/or other form of browser-executable code. *See Office Action*, p. 2 (14 Oct 2009).

Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication 2002/0065509 ("Lebel") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 4 (14 Oct 2009).

Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,944,659 ("Labbe") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 6 (14 Oct 2009).

Claims 1, 10-16, 18, 19, 23, 24, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,296,638 ("Davison") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 8 (14 Oct 2009).

Claims 1 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,086,528 ("Adair") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 9 (14 Oct 2009).

Without any prejudice or disclaimer, moreover, Applicant hereby amends Claims 1, 67, and 68 and newly presents Claims 69-71. These changes were made to further clarify patentable subject matter set forth in the specification as originally filed. No new matter has been added.

Support for the amendments and new claim(s) can be found, *inter alia,* at Figure 5, Paragraph 0027, Paragraph 0034, Paragraph 0035, Paragraph 0036, and Paragraph 0041.

II. DRAWING OBJECTIONS

The drawings stand objected under 37 CFR §1.121(d). *See Office Action*, p. 2 (14 Oct 2009). According to the Examiner, the previously-submitted drawings are "elementary in nature," "not sufficient to describe the invention," and "Figure 3 appears to be comprised of 3 separate figures, none of which is currently labeled independently (i.e.: 3A, 3B, and 3C)."

Applicant respectfully submits that Applicant has reviewed 37 CFR § 1.84 entitled "Standards for drawings." Applicant can find no requirement that formal drawings be non-"elementary." In fact, legibility and suitability for reproduction appear to be the cornerstone requirements of 37 CFR § 1.84. Therefore, Applicant respectfully traverses the Examiner's objections to the drawings as being "elementary in nature."

Similarly, Applicant respectfully traverses the Examiner's objections to the drawings as being "not sufficient to describe the invention." The Patent Office and/or the Examiner has conducted examination of the subject application since April 19, 2004, and while Applicant and the Examiner have not yet agreed on the proper scope of allowable subject matter, this disagreement does not in any way be attributable to the Examiner's inability to understand the claims or specification of the subject application, but rather, are based on disagreements pertaining to the relevant teachings of the prior art. Applicant respectfully submits, and requests that the Examiner thoughtfully consider, whether the subject drawings are in fact sufficient to describe the invention. For the foregoing reasons, Applicant respectfully traverses the Examiner's objections to the drawings as being "not sufficient to describe the invention."

In partial satisfaction of the Examiner's continued requirement for replacement formal drawings, , Applicant hereby submits concurrently herewith Second Replacement Formal Drawings. Applicant has addressed the Examiner's concern that "Figure 3 appears to be comprised of 3 separate figures, none of which is currently labeled independently (i.e.: 3A, 3B, and 3C)" by independently labeling the three sub-figures shown on Sheet 3. No new matter has been added. Therefore, Applicant respectfully requests reconsideration and withdrawal of the objections to the drawings.

III. SPECIFICATION OBJECTION

The specification stands objected under MPEP §608.01 as containing an embedded hyperlink. *See Office Action*, p. 2 (14 Oct 2009). Without waiving any right to contest this objection in any future response, Applicant hereby amends the specification as set forth above. In addition, Applicant has amended the specification to reflect the above-noted re-labeling of the drawing(s) shown on Sheet 3 of the Second Replacement Formal Drawings. Applicant respectfully requests entrance of this amendment and removal of the objection.

IV. ISSUES TO BE REVIEWED

The issues in this response relate to whether the art of record establishes a *prima facie* case of the unpatentability of Applicant's claims. For reasons set forth elsewhere herein, Applicant respectfully asserts that the art of record does not establish a *prima facie* case of the unpatentability of any pending claim.[1] Accordingly, Applicant respectfully requests that the USPTO hold all pending claims allowable for at least the reasons described herein, and issue a Notice of Allowance on same.

V. ARGUMENT: ART OF RECORD DOES NOT ESTABLISH *PRIMA FACIE* CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD

The USPTO has stated that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication 2002/0065509 ("Lebel") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 4 (14 Oct 2009). The USPTO has further stated that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,944,659 ("Labbe") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 6 (14 Oct 2009). The USPTO has further stated that Claims 1, 10-16, 18, 19, 23, 24, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,296,638 ("Davison") in view of U.S.

[1] Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.,* 37 C.F.R. § 10.83 ("A practitioner should represent a client zealously within the bounds of the law."); 37 C.F.R. § 10.84 ("[A] practitioner shall not intentionally … [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part."); and 37 C.F.R. § 10.76 ("A practitioner should represent a client competently."). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the Examiner's behalf.

Publication 2005/0004553 ("Douk"). *See Office Action*, p. 8 (14 Oct 2009). The USPTO has further stated that Claims 1 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,086,528 ("Adair") in view of U.S. Publication 2005/0004553 ("Douk"). *See Office Action*, p. 9 (14 Oct 2009).

In response, Applicant respectfully asserts herein that, under the MPEP and legal standards for patentability as previously set forth in Applicant's Response to Examiner's June 23, 2009 Office Action, the art of record does not establish a *prima facie* case of the unpatentability of Applicant's claims at issue. Specifically, Applicant respectfully shows below that the art of record does not recite the text of Applicant's claims at issue, and hence fails to establish a *prima facie* case of unpatentability. Accordingly, Applicant respectfully requests that the USPTO withdraw its rejections and hold all claims to be allowable over the art of record.

A. Technical Material Cited by the USPTO Does Not Show/Suggest Recitations of Independent Claim 1 and Dependent Claims 2-34 and 66-71 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites as follows:

1. A device for perfusion management, comprising:

[a] a body portion;

[b] at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion;

[c] at least one reservoir in communication with said extensible finger; and

[d] a control circuitry coupled to said extensible finger, and/or said body portion,

[e] wherein the device for perfusion management is configured for full placement in vivo and

[f] wherein the plurality of retractable segments of the extensible finger are configured while in vivo to controllably telescopically extend from the body

portion under control of the control circuitry without requiring physical access by an individual.[2]

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference "teaches" at least some of the text of Independent Claim 1, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Independent Claim 1. Moreover, Applicant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render the cited art unfit for one or more of its intended purposes.

2. Davison and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) The USPTO is Characterizing/Asserting Davison and Douk to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

> Davison et al disclose a device comprising a body portion (1); at least one extensible finger (42) coupled to said body portion; at least one reservoir (32) in communication with said extensible finger; and a control circuitry (Col. 17, lines 40-49) coupled to said body portion.
>
> Davison et al. do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16,

[2] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

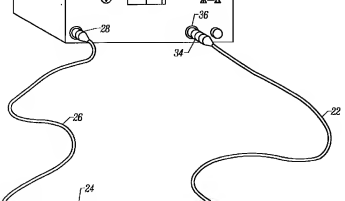
Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Davison et al, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 8 (14 Oct 2009).[3] Applicant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Davison "Teaches" Recitations of Independent Claim 1

Applicant respectfully points out that Applicant has reviewed the Davison reference identified by the USPTO, and so far as Applicant can discern, the Davison reference does not recite "[e] wherein the device for perfusion management is **configured for full placement in vivo**" as recited in Applicant's Independent Claim 1.[4] Rather, the portions of Davison cited by the USPTO actually recite as follows:



[3] Applic laims, but app aterial. Accordi unpaten onstrates herein t unpaten

[4] Nor d gation of the MP

> Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode.
>
> *See Davison*, Figure 1 and Col. 17, Lines 40-49.

The USPTO is characterizing Davison to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference "teaches" is a question of fact.[5,6,7] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do

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[5] *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[6] *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[7] Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[8] *In re Lee,* 277 F.3d 1338 (Fed. Cir. 2002);[9] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[10] Even if the PTO personnel

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[8] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.'" *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[9] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[10] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term

were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[11] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[12,13,14,15] For each instance below in which the

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> "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[11] *See Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

[12] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Davison do *not recite* the text of at least Clause [e] of Independent Claim 1: "wherein the device for perfusion management is **configured for full placement in vivo.**"

Instead, Davison further recites in reference to Figure 1 above that:

> The electrosurgical probe will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode terminal(s). **The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft.** The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. The distal portion of the shaft may comprise a flexible material, such as plastics, malleable stainless steel, etc, **so that the physician can mold the distal portion into different configurations for different applications**. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 0.5 mm and frequently in the range from 1 to 10 mm. **Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.**
>
> For procedures within the nose and joints, **the shaft will have a suitable diameter and length to allow the surgeon to reach the target by delivering the probe shaft through an percutaneous opening in the patient** (e.g., a portal

[13] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[14] *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

[15] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

formed in the joint in arthroscopic surgery, or through one of the patient's nasal passages in FESS). Thus, the shaft will usually have a length in the range of about 5-25 cm, and a diameter in the range of about 0.5 to 5 mm. For procedures requiring the formation of a small hole or channel in tissue, such as treating swollen turbinates, the shaft diameter will usually be less than 3 mm, preferably less than about 1 mm. Likewise, for procedures in the ear, the shaft should have a length in the range of about 3 to 20 cm, and a diameter of about 0.3 to 5 mm. **For procedures in the mouth or upper throat, the shaft will have any suitable length and diameter that would facilitate handling by the surgeon**. For procedures in the lower throat, such as laryngectomies, the shaft will be suitably designed to access the larynx. For example, the shaft may be flexible, or have a distal bend to accommodate the bend in the patient's throat. In this regard, the shaft may be a rigid shaft having a specifically designed bend to correspond with the geometry of the mouth and throat, or it may have a flexible distal end, or it may be part of a catheter. In any of these embodiments, the shaft may also be introduced through rigid or flexible endoscopes. Specific shaft designs will be described in detail in connection with the figures hereinafter.

See Davison, Col. 12, Line 38 – Col. 13, Line 25 (emphasis added).

Applicant has shown by direct quotations that Independent Claim 1 and the Davison reference are very different on their faces. *See supra* (quotation of Claim 1 and quotation of Davison). Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different from Claim 1, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See Applicant's Response to Examiner's June 23, 2009 Office Action.*

Accordingly, insofar as that Davison does not recite the text of at least Clause [e] of Applicant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Davison could be modified/combined to teach at least Clause [e] of Independent Claim 1, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent

Claim 1 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

b) Modifications/Combinations to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components of Cited References; No Teaching to Combine/Modify Components as a Matter of Law.

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Davison to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standards there can be no teaching to modify/combine the technology of Davison as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology.

(1) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention

required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Applicant respectfully asserts that one reason for Davison's lack of disclosure of "[e] wherein the device for perfusion management is **configured for full placement in vivo"** may be gleaned from principles of operation indicated in this recitation:

> Referring now to FIG. 1, an exemplary electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue will now be described in detail. As shown, electrosurgical system 5 generally includes **an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more electrode terminals and a loop electrode** (not shown in FIG. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. **Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40.** Power supply 10 also includes one or more **foot pedals 24** and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. **The foot pedal 24 may also include a second pedal** (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and **a third pedal (also not shown) for switching between an ablation mode and a coagulation mode**.

See Davison, Col. 17, Lines 29-49 (emphasis added).

Applicant respectfully points out that were one to incorporate "wherein the device for perfusion management is **configured for full placement in vivo**" of Claim 1 into the structure of Davison, Davison would no longer provide "**an electrosurgical probe 20 connected to a power supply 10 … Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40 … Power supply 10 also includes one or more foot pedals 24 … a second pedal … a third pedal.**" Thus, any modifications/combinations would change the principle of operation of Davison for at least this reason.

As discussed above, one reason why such modified Davison technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Davison technology to provide "[e] wherein the device for perfusion management is **configured for full placement in vivo**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Davison.

As has been shown above, any modification of Davison would require "substantial reconstruction and redesign of the elements shown in [... Davison] as well as a change in the basic principle under which the [... Davison] construction was designed to operate" in order to reach the recitations of Claim 1.[16] Accordingly, insofar as that any modification to Davison would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Davison.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Davison capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Davison will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Independent Claim 1 patentable and issue a Notice of Allowance of Applicant's Independent Claim 1 for at least the foregoing reasons.

[16] This statement reflects Applicant's current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Davison's intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

3. Adair and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) The USPTO is Characterizing/Asserting Adair and Douk to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

Adair teaches a body (handle), an extending part (probe), at least one receiving body (syringe) and a control circuit.

Adair does not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Adair, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 10 (14 Oct 2009).[17] Applicant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Adair "Teaches" Recitations of Independent Claim 1

Applicant respectfully points out that Applicant has reviewed the Adair reference identified by the USPTO, and so far as Applicant can discern, the Adair reference does not recite "[e] wherein the device for perfusion management is **configured for full placement in vivo**" as recited in Applicant's Independent Claim 1.[18] Rather, the portions of Adair cited by the USPTO actually recite as follows:

Examiner did not cite to any specific portions of Adair.

The USPTO is characterizing Adair to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference "teaches" is a question of fact.[19,20,21] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective

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[17] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

[18] Nor does Adair recite as the USPTO alleges, for that matter; Applicant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Applicant's Independent Claim 1.

[19] *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact,.. Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[20] *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[21] Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[22] *In re Lee,* 277 F.3d 1338 (Fed. Cir. 2002);[23] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[24] Even if the PTO

[22] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.'" *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[23] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[24] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term

personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[25] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[26,27,28,29] For each instance below in which the

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> "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[25] *See Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

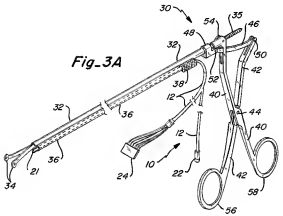
[26] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

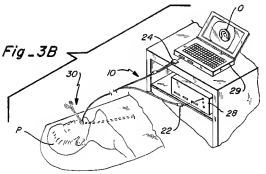
> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Adair do *not recite* the text of at least Clause [e] of Independent Claim 1: "wherein the device for perfusion management is **configured for full placement in vivo.**"

Instead, Adair illustrates and recites that:





[27] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[28] *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

[29] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

In one application, the microendoscope of this invention may be **used in conjunction with standard Jackson grasping forceps** which have been modified to include a longitudinal tube or channel for which to receive the microendoscope. In use, the microendoscope provides an integral imaging capability **while the surgeon manipulates the Jackson grasping forceps for removal of a foreign object within a patient**.

The first application of the microendoscope is illustrated in FIGS. 3A and 3B. As shown, the microendoscope 10 may be used with modified Jackson grasping forceps 30. The particular grasping forceps 30 illustrated in FIG. 3A is characterized by an instrument channel 32 which may receive therethrough a pair of elongate grasping tines 34. The grasping tines 34 terminate at the proximal end by forming a single tine rod 35. Grasping tines 34 may be slid inwardly or outwardly within instrument channel 32 by the scissor action of first member 40 and second member 42. The first and second members 40 and 42 connect at pivot point 44. The distal end of second member 42 includes a push link 46 attached thereto at one end by means of pin 50. The other end of push link 46 is connected to bracket 48 by means of pin 52. As rings 56 and 58 of members 42 and 40 are pressed together by the fingers of a surgeon, first member 40 will cause the grasping tines 34 to be moved in a rearward or proximal direction such that the normally separated or open distal ends of tines 34 are pressed or drawn together by their proximal movement into the instrument channel 32. When it is desired to have the tines 34 protrude from the instrument channel 32, rings 56 and 58 are again separated. The forceps are able to grasp a foreign object by the open-close action of the tines 34. Conveniently, tightening knob 54 may be provided so that first member 40 may be positioned at a desired location along tine rod 35. The particular positioning of first member 40 along tine rod 35 enables the grasping tines 34 to protrude a desired distance beyond the distal end of instrument channel 32.

The grasping forceps 30 are modified to include an endoscope tube 36 which receives the microendoscope 10. The tube 36 may be welded or glued alongside channel 32, or attached by other well-known means. Conveniently, the endoscope tube 36 may include a tightening knob or adjustment member 38 to control the extent to which the distal end 21 of the endoscope 10 protrudes beyond the distal end of the endoscope tube 36. Placement of the microendoscope directly alongside the forceps enables the microendoscope to view the tines as they are manipulated to grasp the foreign object. The forward or distal placement of the microendoscope also enables it to view the path of insertion into the patient.

As shown in FIG. 3B, the Jackson grasping forceps are inserted into the patient P to remove a foreign object O which can be viewed on the screen of the video control device 29. From the surgery being performed in FIG. 3B, a foreign object such as a coin may be removed from the lungs or trachea of the

> patient P by means of the Jackson grasping forceps 30. In the past, an instrument such as a full-sized Jackson grasping forceps could not be introduced simultaneously with an endoscope because the trachea or throat of the patient could not accommodate the simultaneous introduction of both the forceps and the endoscope. Therefore, this procedure previously had to be conducted without the surgeon being able to visualize the Jackson grasping forceps as it was introduced into and through the path in the patient's body prior to reaching the surgical site under investigation. Because of the small size of the microendoscope 10, the addition of endoscope tube 36 makes it possible for the Jackson grasping forceps to have the integral imaging capability. In the operation depicted in FIG. 3B, the Jackson grasping device is the preferred surgical instrument since large objects such as coins require removal by tines of substantial size and strength as found only with such forceps. In other words, smaller forceps which may be introduced through a channel of standard endoscopes do not have the grasping strength or size to hold a relatively large foreign object such as a coin.

See Adair, Col. 2, Lines 18-25 and Col. 6, Line 24 – Col. 7, Line 24 (emphasis added).

Applicant has shown by direct quotations that Independent Claim 1 and the Adair reference are very different on their faces. *See supra* (quotation of Claim 1 and quotation of Adair). Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different from Claim 1, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See Applicant's Response to Examiner's June 23, 2009 Office Action.*

Accordingly, insofar as that Adair does not recite the text of at least Clause [e] of Applicant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Adair could be modified/combined to teach at least Clause [e] of Independent Claim 1, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

b) Modifications/Combinations to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components of Cited References; No Teaching to Combine/Modify Components as a Matter of Law.

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Adair to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standards there can be no teaching to modify/combine the technology of Adair as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology.

(1) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic

principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Applicant respectfully asserts that one reason for Adair's lack of disclosure of "[e] wherein the device for perfusion management is **configured for full placement in vivo"** may be gleaned from principles of operation indicated in this recitation:

> In one application, the microendoscope of this invention may be **used in conjunction with standard Jackson grasping forceps** which have been modified to include a longitudinal tube or channel for which to receive the microendoscope. In use, the microendoscope provides an integral imaging capability **while the surgeon manipulates the Jackson grasping forceps for removal of a foreign object within a patient**.

See Adair, Col. 2, Lines 18-25 (emphasis added).

Applicant respectfully points out that were one to incorporate "wherein the device for perfusion management is **configured for full placement in vivo**" of Claim 1 into the structure of Adair, Adair would no longer provide "**standard Jackson grasping forceps which have been modified to include a longitudinal tube or channel for which to receive the microendoscope ... the microendoscope provides an integral imaging capability while the surgeon manipulates the Jackson grasping forceps for removal of a foreign object within a patient**." Thus, any modifications/combinations would change the principle of operation of Adair for at least this reason.

As discussed above, one reason why such modified Adair technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Adair technology to provide "[e] wherein the device for perfusion management is **configured for full placement in vivo**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Adair.

As has been shown above, any modification of Adair would require "substantial reconstruction and redesign of the elements shown in [...Adair] as well as a change in the basic principle under which the [...Adair] construction was designed to operate" in order to reach the

recitations of Claim 1.[30] Accordingly, insofar as that any modification to Adair would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Adair.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Adair capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Adair will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Independent Claim 1 patentable and issue a Notice of Allowance of Applicant's Independent Claim 1 for at least the foregoing reasons.

4. Lebel and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) The USPTO is Characterizing/Asserting Lebel and Douk to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

> Lebel et al teach a device comprising a body portion (6); at least one extensible finger (16) coupled to said body portion; at least one reservoir (84) in communication with said extensible finger; and a control circuitry (Paragraph [0140]) coupled to said body portion.

[30] This statement reflects Applicant's current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Adair's intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

> Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).
>
> At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 5 (14 Oct 2009).[31] Applicant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Douk "Teaches" Recitations of Independent Claim 1

Applicant agrees with the USPTO's statement that, "Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion."

[31] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

Furthermore, Applicant respectfully points out that Applicant has reviewed the Douk reference identified by the USPTO, and so far as Applicant can discern, the Douk reference also does not recite "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" as recited in Applicant's Independent Claim 1.[32] Rather, the portions of Douk cited by the USPTO actually recite as follows:

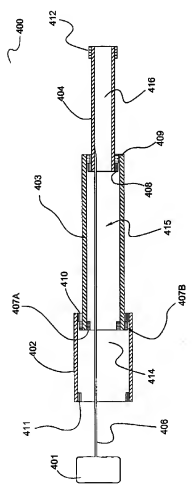


FIG. 4

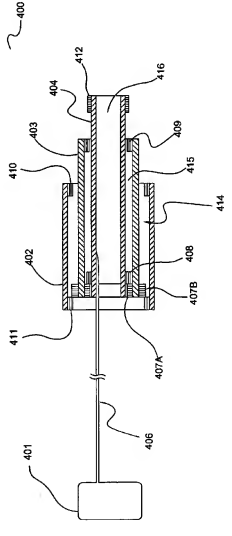


FIG. 5

[32] Nor does Douk recite as the USPTO alleges, for that matter; Applicant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Applicant's Independent Claim 1.

See Douk, Figures 4 and 5.

The USPTO is characterizing Douk to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference "teaches" is a question of fact.[33,34,35] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[36] *In re Lee,* 277 F.3d

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[33] *See Rapoport v. Dement,* 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact,.. Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[34] *In re Bell***,** 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[35] Anticipation**,** as well as what a reference teaches**,** is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[36] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

1338 (Fed. Cir. 2002);[37] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[38] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[39] Thus, when a party to a matter asserts that a

[37] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[38] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[39] *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to**

reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[40,41,42,43] For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Douk do *not recite* the text of at least Clause [f] of Independent Claim 1: "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual.**"

Instead, Douk further illustrates and recites that:

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prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.") (emphasis added)

[40] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[41] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[42] *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009).

[43] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

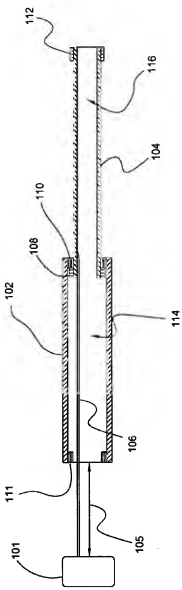

FIG. 1

[0024] **As shown in FIG. 1, positioning wire 106 extends from grip portion 101, through lumen 114 of proximal tubular element 102, into lumen 116 of distal tubular element 104. Positioning wire 106 is a long, thin wire, such as a guidewire or a core wire. As catheter 100 may be extended from a fully nested condition to a fully extended condition in vivo, positioning wire 106 must be sufficiently stiff as to push distal tubular element through the tortuous vasculature and yet flexible enough to navigate the same tortuous vasculature.** Any material known in the art for use as a guidewire is appropriate for positioning wire 106. Examples of such materials include stainless steel, nitinol alloys, or polymeric materials. In one embodiment, positioning wire 106 is a solid wire. In another embodiment, positioning wire 106 is a hollow tube.

[0025] **The length of positioning wire 106 may vary depending upon the design, but positioning wire 106 must be of sufficient length such that a proximal portion 105 thereof extends proximally of a proximal end of proximal tubular element 102, even when catheter 100 is fully extended. For the purposes of illustration only, if catheter 100 is 135 cm, the typical length of a PTCA or coronary intervention catheter, then positioning wire 106 for such a catheter would be approximately 140 cm.**

[0026] **Proximal tubular element 102 is slidably mounted over positioning wire 106. A distal end of positioning wire 106 is fixedly attached to** distal **tubular element 104.** In one embodiment, as shown in FIG. 1, the distal end of positioning wire 106 is fixedly attached to an inner surface of distal tubular element 104. Alternately, the distal end of positioning wire 106 may be attached to a proximal tip of distal tubular element 104, or even to a proximal stop 108 disposed on a proximal end of distal tubular element 104. The fixed attachment is achieved by any method known in the art, such as by cementing, soldering, or heat bonding. A proximal end of distal tubular element 104 is inserted into a distal end of proximal tubular element 102.

[0030] **Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106.** Any such handle known in the art may be used, such as a molded handle with a textured surface for maintaining the grip, or a more ergonomically designed handle with finger holes. Grip portion 101 may be made from any material known in the art for handles, such as plastic, rubber, or metal. **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly.**

[0031] Operation and use of telescoping sheath catheter 100 as a deployment catheter is now described. The specific details included in the following example are for illustrative purposes only; this type of catheter may be used in a similar manner albeit for a slightly different procedure such as introducing diagnostic or

therapeutic medical devices, with or without such devices being attached to guidewires. During the course of a typical procedure using a distal protection element, such as a collapsible filter or an occluder, **the protection element must reside on the end of a guidewire relative to the treatment position**. In order to reduce the profile of the collapsed filter during launch, the filter and guidewire (not shown) are inserted into catheter 100, which is in the fully extended position. The proximal portion of the guidewire extends beyond the proximal end of catheter 100. **Catheter 100 and the guidewire are then advanced through a patient's cardiovascular system until the filter is positioned at an appropriate location relative to the treatment location, such as downstream of the treatment location.** The sizes of proximal stop 108 and distal stop 110 help to prevent catheter 100 from premature or unintentional contraction during the insertion process.

[0032] At this point, catheter 100 is removed from the patient so that the filter may be deployed and other therapeutic and/or diagnostic catheters may be positioned over the guidewire, such as a balloon catheter. To extract catheter 100 quickly and easily, catheter 100 is contracted into a rapid exchange length, shown in FIG. 3. **The clinician grasps grip portion 101 and draws positioning wire 106 proximally, pulling distal tubular element 104 into proximal tubular element 102 in a telescoping manner.** Distal tubular element 104 is prevented from being pulled through the open proximal end of proximal tubular element 102 by the engagement of proximal stop 108 with stop 111. After the nesting of distal tubular element 104 within proximal tubular element 102 is complete, the effective over-the-wire length of catheter 100 is such that the clinician may withdraw catheter 100 without losing contact with the proximal end of the guidewire.

[0033] If the clinician wishes to use catheter 100 as a retrieval catheter for a medical device, such as a filter guidewire assembly, the clinician would first remove any therapeutic catheters from the guidewire. Catheter 100 is in a "nested" condition, as shown in FIG. 3, and the proximal end of the filter guidewire assembly would be positioned within lumen 116. **The clinician pushes positioning wire 106 distally to extend catheter 100 to the fully extended position shown in FIG. 1.** As it extends, catheter 100 is guided over the guidewire to the filter, which would either be in a collapsed configuration for removal or would be collapsed by passing catheter 100 over the filter. Catheter 100 and the filter guidewire assembly are then removed from the patient as a unit.

[0036] **As shown in FIG. 4, a positioning wire 406 extends from grip portion 401, through lumens 414 and 415 to distal tubular element 404, wherein positioning wire 406 is affixed to a proximal end thereof.** In one embodiment, shown in FIG. 4, positioning wire 406 extends into lumen 416 and is fixedly attached to an inner wall of distal tubular element 404. Positioning wire 406 is a flexible wire, such as a guidewire or core wire, and any material known in the art

for use as a guidewire is appropriate for its use. Examples of such materials include but are not limited to stainless steel or nitinol alloys.

[0038] **A grip portion 401 is a handle for the clinician to grasp and manipulate positioning wire 406. As with grip portion 101 described above with respect to FIG. 1, any handle known in the art may be used. Alternatively, grip portion 401 may be eliminated entirely, and the clinician will simply grasp positioning wire 406 directly.**

[0050] The operation and use of catheter 400 as either a deployment or retrieval catheter is very similar to that of catheter 100, described above. When determining the effective over-the-wire length of catheter 100 after insertion, the clinician can choose to extend catheter 400 to any of the lengths available: fully extended or partially extended. **Also, for rapid exchange, the clinician may choose to fully retract catheter 400 by drawing positioning wire 406 proximally until catheter 400 is in the fully nested position,** or only partially, until one of the partially extended positions is achieved.

See Douk at referenced paragraphs (emphasis added).

Applicant has shown by direct quotations that Independent Claim 1 and the Douk reference are very different on their faces. *See supra* (quotation of Claim 1 and quotation of Douk). Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different from Claim 1, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See Applicant's Response to Examiner's June 23, 2009 Office Action.*

Accordingly, insofar as that neither Douk nor Lebel recites the text of at least Clause [f] of Applicant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Douk or Lebel could be modified/combined to teach at least Clause [f] of Independent Claim 1, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent

Claim 1 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

a) Modifications/Combinations to Meet the Recitations of Independent Claim 1 are Conclusory Statements; Change the Principle of Operation of Components of Cited References; and Render Cited References Unfit for Intended Purposes; No Teaching to Combine/Modify Components as a Matter of Law.

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine the cited references to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standard the USPTO's statements appear to be conclusory statements without evidentiary support, there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology, and there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination renders the technology unfit for one or more of its intended purposes.

(1) The USPTO Assertions Regarding A Teaching to Modify/Combine to Meet the Recitations of Independent Claim 1 Are Based on "Mere Conclusory Statements" Without Evidentiary Support

As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's "***analysis should be made explicit***" ... [***and*** that] rejections ... ***cannot be sustained by mere conclusory statements***; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

Concerning Claim 1, the USPTO has stated as follows:

Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 5 (14 Oct 2009).

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Lebel and Douk references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a "mere conclusory statement." Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

(2) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee

taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Applicant respectfully asserts that one reason for Douk's lack of disclosure of "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" may be gleaned from principles of operation indicated in this recitation:

[0030] **Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106.** Any such handle known in the art may be used, such as a molded handle with a textured surface for maintaining the grip, or a more ergonomically designed handle with finger holes. Grip portion 101 may be made from any material known in the art for handles, such as plastic, rubber, or metal. **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly.**

[0031] Operation and use of telescoping sheath catheter 100 as a deployment catheter is now described. The specific details included in the following example are for illustrative purposes only; this type of catheter may be used in a similar manner albeit for a slightly different procedure such as introducing diagnostic or therapeutic medical devices, with or without such devices being attached to guidewires. During the course of a typical procedure using a distal protection element, such as a collapsible filter or an occluder, **the protection element must reside on the end of a guidewire relative to the treatment position**. In order to reduce the profile of the collapsed filter during launch, the filter and guidewire (not shown) are inserted into catheter 100, which is in the fully extended position. The proximal portion of the guidewire extends beyond the proximal end of catheter 100. **Catheter 100 and the guidewire are then advanced through a patient's cardiovascular system until the filter is positioned at an appropriate location relative to the treatment location, such as downstream of the treatment location.** The sizes of proximal stop 108 and distal stop 110 help to prevent catheter 100 from premature or unintentional contraction during the insertion process.

See Douk, Paragraphs 0030 and 0031 (emphasis added).

Applicant respectfully points out that were one to incorporate "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" of Claim 1 into the structure of Douk, Douk would no longer provide "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106 ... Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**." Thus, any modifications/combinations would change the principle of operation of Douk for at least this reason.

As discussed above, one reason why such modified Douk technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Douk technology to provide "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Douk.

As has been shown above, any modification of Douk would require "substantial reconstruction and redesign of the elements shown in [...Douk] as well as a change in the basic principle under which the [...Douk] construction was designed to operate" in order to reach the recitations of Claim 1.[44] Accordingly, insofar as that any modification to Douk would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Douk.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Douk capable of performing the intended purposes,

[44] This statement reflects Applicant's current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Douk's intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

under the MPEP guidelines as set forth above, the theory of operation of the technologies of Douk will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Independent Claim 1 patentable and issue a Notice of Allowance of Applicant's Independent Claim 1 for at least the foregoing reasons.

(3) Modifications to Meet the Recitations of Independent Claim 1 Render Components Being Modified Unsatisfactory for their Intended Purposes; No Teaching to Modify/Combine Components as a Matter of Law.

Furthermore, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE
>
> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

As noted above, the USPTO has stated as follows:

> Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> **At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion**.
>
> Office Action, p. 5 (14 Oct 2009). [45]

Applicant again points out that the USPTO has provided no evidence to modify/combine the cited technical materials to reach the recitations of Independent Claim 1. Even assuming, ***arguendo***, that the USPTO had produced an as-yet-unknown objective teaching of how to modify/combine the structure of Lebel with the technology of Douk to create "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" (as set forth in Independent Claim 1) such a modification/combination would apparently render the technology of Lebel unsatisfactory for one or more of its intended purposes.

Lebel recites, "**An implantable infusion pump** possesses operational functionality that is, at least in part, controlled by software operating in two processor ICs which are configured to perform some different and some duplicate functions." *See Lebel*, Abstract (emphasis added). It

[45] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

is unclear, at best, how this purpose could be served in conjunction with "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106** ... **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**" as recited by Douk. Thus, for at least this reason, the suggested modifications/combinations would render the technology of Lebel unsatisfactory for one or more of its intended purposes. There can thus be no teaching to modify/combine such references to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, and in light of the MPEP standards for patentability as set forth above, Applicant respectfully requests that the USPTO hold Applicant's Independent Claim 1 patentable and issue a Notice of Allowance of Independent Claim 1 for at least the reasons set forth herein.

5. Labbe and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) The USPTO is Characterizing/Asserting Labbe and Douk to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

Labbe et al disclose a device comprising a body portion (3); at least one extensible finger (2) coupled to said body portion; at least one reservoir (12) in communication with said extensible finger; and a control circuitry (Figure 4) coupled to said body portion.

Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the

segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 6 (14 Oct 2009).[46] Applicant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Douk "Teaches" Recitations of Independent Claim 1

Applicant agrees with the USPTO's statement that, "Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion."

Furthermore, Applicant respectfully points out that Applicant has reviewed the Douk reference identified by the USPTO, and so far as Applicant can discern, the Douk reference also does not recite "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" as

[46] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

recited in Applicant's Independent Claim 1.[47] Rather, the portions of Douk cited by the USPTO actually recite as follows:

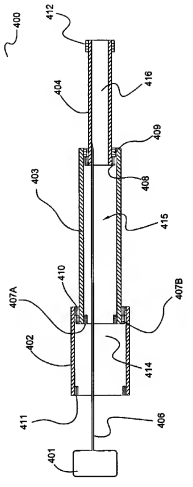

FIG. 4

[47] Nor does Douk recite as the USPTO alleges, for that matter; Applicant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Applicant's Independent Claim 1.

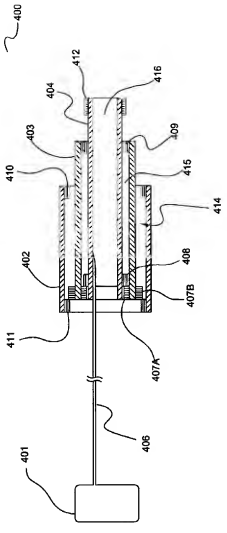

FIG. 5

See Douk, Figures 4 and 5.

The USPTO is characterizing Douk to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for

Independent Claim 1. What a reference "teaches" is a question of fact.[48,49,50] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);[51] *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);[52] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto.

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[48] *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact,... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[49] *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[50] Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[51] In *McNeil*, the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[52] In *Lee*, the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

… Broad conclusory statements standing alone are not "evidence.").[53] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[54] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be

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[53] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[54] *See Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

no finding of fact in favor of the asserted teaching.[55,56,57,58] For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Douk do *not recite* the text of at least Clause [f] of Independent Claim 1: "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual.**"

Instead, Douk further illustrates and recites that:

[55] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[56] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[57] *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009).

[58] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

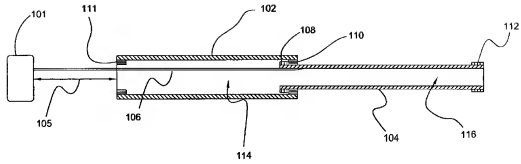

FIG. 1

[0024] **As shown in FIG. 1, positioning wire 106 extends from grip portion 101, through lumen 114 of proximal tubular element 102, into lumen 116 of distal tubular element 104. Positioning wire 106 is a long, thin wire, such as a guidewire or a core wire. As catheter 100 may be extended from a fully nested condition to a fully extended condition in vivo, positioning wire 106 must be sufficiently stiff as to push distal tubular element through the tortuous vasculature and yet flexible enough to navigate the same tortuous vasculature.** Any material known in the art for use as a guidewire is appropriate for positioning wire 106. Examples of such materials include stainless steel, nitinol alloys, or polymeric materials. In one embodiment, positioning wire 106 is a solid wire. In another embodiment, positioning wire 106 is a hollow tube.

[0025] **The length of positioning wire 106 may vary depending upon the design, but positioning wire 106 must be of sufficient length such that a proximal portion 105 thereof extends proximally of a proximal end of proximal tubular element 102, even when catheter 100 is fully extended. For the purposes of illustration only, if catheter 100 is 135 cm, the typical length of a PTCA or coronary intervention catheter, then positioning wire 106 for such a catheter would be approximately 140 cm.**

[0026] **Proximal tubular element 102 is slidably mounted over positioning wire 106. A distal end of positioning wire 106 is fixedly attached to distal tubular element 104.** In one embodiment, as shown in FIG. 1, the distal end of positioning wire 106 is fixedly attached to an inner surface of distal tubular element 104. Alternately, the distal end of positioning wire 106 may be attached to a proximal tip of distal tubular element 104, or even to a proximal stop 108

disposed on a proximal end of distal tubular element 104. The fixed attachment is achieved by any method known in the art, such as by cementing, soldering, or heat bonding. A proximal end of distal tubular element 104 is inserted into a distal end of proximal tubular element 102.

[0030] **Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106.** Any such handle known in the art may be used, such as a molded handle with a textured surface for maintaining the grip, or a more ergonomically designed handle with finger holes. Grip portion 101 may be made from any material known in the art for handles, such as plastic, rubber, or metal. **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly.**

[0031] Operation and use of telescoping sheath catheter 100 as a deployment catheter is now described. The specific details included in the following example are for illustrative purposes only; this type of catheter may be used in a similar manner albeit for a slightly different procedure such as introducing diagnostic or therapeutic medical devices, with or without such devices being attached to guidewires. During the course of a typical procedure using a distal protection element, such as a collapsible filter or an occluder, **the protection element must reside on the end of a guidewire relative to the treatment position**. In order to reduce the profile of the collapsed filter during launch, the filter and guidewire (not shown) are inserted into catheter 100, which is in the fully extended position. The proximal portion of the guidewire extends beyond the proximal end of catheter 100. **Catheter 100 and the guidewire are then advanced through a patient's cardiovascular system until the filter is positioned at an appropriate location relative to the treatment location, such as downstream of the treatment location.** The sizes of proximal stop 108 and distal stop 110 help to prevent catheter 100 from premature or unintentional contraction during the insertion process.

[0032] At this point, catheter 100 is removed from the patient so that the filter may be deployed and other therapeutic and/or diagnostic catheters may be positioned over the guidewire, such as a balloon catheter. To extract catheter 100 quickly and easily, catheter 100 is contracted into a rapid exchange length, shown in FIG. 3. **The clinician grasps grip portion 101 and draws positioning wire 106 proximally, pulling distal tubular element 104 into proximal tubular element 102 in a telescoping manner.** Distal tubular element 104 is prevented from being pulled through the open proximal end of proximal tubular element 102 by the engagement of proximal stop 108 with stop 111. After the nesting of distal tubular element 104 within proximal tubular element 102 is complete, the effective over-the-wire length of catheter 100 is such that the clinician may withdraw catheter 100 without losing contact with the proximal end of the guidewire.

[0033] If the clinician wishes to use catheter 100 as a retrieval catheter for a medical device, such as a filter guidewire assembly, the clinician would first remove any therapeutic catheters from the guidewire. Catheter 100 is in a "nested" condition, as shown in FIG. 3, and the proximal end of the filter guidewire assembly would be positioned within lumen 116. **The clinician pushes positioning wire 106 distally to extend catheter 100 to the fully extended position shown in FIG. 1.** As it extends, catheter 100 is guided over the guidewire to the filter, which would either be in a collapsed configuration for removal or would be collapsed by passing catheter 100 over the filter. Catheter 100 and the filter guidewire assembly are then removed from the patient as a unit.

[0036] **As shown in FIG. 4, a positioning wire 406 extends from grip portion 401, through lumens 414 and 415 to distal tubular element 404, wherein positioning wire 406 is affixed to a proximal end thereof.** In one embodiment, shown in FIG. 4, positioning wire 406 extends into lumen 416 and is fixedly attached to an inner wall of distal tubular element 404. Positioning wire 406 is a flexible wire, such as a guidewire or core wire, and any material known in the art for use as a guidewire is appropriate for its use. Examples of such materials include but are not limited to stainless steel or nitinol alloys.

[0038] **A grip portion 401 is a handle for the clinician to grasp and manipulate positioning wire 406. As with grip portion 101 described above with respect to FIG. 1, any handle known in the art may be used. Alternatively, grip portion 401 may be eliminated entirely, and the clinician will simply grasp positioning wire 406 directly.**

[0050] The operation and use of catheter 400 as either a deployment or retrieval catheter is very similar to that of catheter 100, described above. When determining the effective over-the-wire length of catheter 100 after insertion, the clinician can choose to extend catheter 400 to any of the lengths available: fully extended or partially extended. **Also, for rapid exchange, the clinician may choose to fully retract catheter 400 by drawing positioning wire 406 proximally until catheter 400 is in the fully nested position,** or only partially, until one of the partially extended positions is achieved.

See Douk at referenced paragraphs (emphasis added).

Applicant has shown by direct quotations that Independent Claim 1 and the Douk reference are very different on their faces. *See supra* (quotation of Claim 1 and quotation of Douk). Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different

from Claim 1, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See Applicant's Response to Examiner's June 23, 2009 Office Action.*

Accordingly, insofar as that neither Douk nor Labbe recites the text of at least Clause [f] of Applicant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Douk or Labbe could be modified/combined to teach at least Clause [f] of Independent Claim 1, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

b) Modifications/Combinations to Meet the Recitations of Independent Claim 1 are Conclusory Statements; Change the Principle of Operation of Components of Cited References; and Render Cited References Unfit for Intended Purposes; No Teaching to Combine/Modify Components as a Matter of Law.

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine the cited references to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standard the USPTO's statements appear to be conclusory statements without evidentiary support, there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology, and there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination renders the technology unfit for one or more of its intended purposes.

(1) The USPTO Assertions Regarding A Teaching to Modify/Combine to Meet the Recitations of Independent Claim 1 Are Based on "Mere Conclusory Statements" Without Evidentiary Support

As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's "***analysis should be made explicit***" ... [***and*** that] rejections ... ***cannot be sustained by mere conclusory statements***; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

Concerning Claim 1, the USPTO has stated as follows:

> Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> **At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.**

Office Action, p. 6 (14 Oct 2009).[59]

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Labbe and Douk references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a

[59] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

"mere conclusory statement." Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

(2) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate," 270 F.2d at 813, 123 USPQ at 352.).

Applicant respectfully asserts that one reason for Douk's lack of disclosure of "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" may be gleaned from principles of operation indicated in this recitation:

> [0030] **Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106.** Any such handle known in the art may be used, such as a molded handle with a textured surface for maintaining the grip, or a more ergonomically designed handle with finger holes. Grip portion 101 may be made

from any material known in the art for handles, such as plastic, rubber, or metal. **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly.**

[0031] Operation and use of telescoping sheath catheter 100 as a deployment catheter is now described. The specific details included in the following example are for illustrative purposes only; this type of catheter may be used in a similar manner albeit for a slightly different procedure such as introducing diagnostic or therapeutic medical devices, with or without such devices being attached to guidewires. During the course of a typical procedure using a distal protection element, such as a collapsible filter or an occluder, **the protection element must reside on the end of a guidewire relative to the treatment position**. In order to reduce the profile of the collapsed filter during launch, the filter and guidewire (not shown) are inserted into catheter 100, which is in the fully extended position. The proximal portion of the guidewire extends beyond the proximal end of catheter 100. **Catheter 100 and the** guidewire **are then advanced through a patient's cardiovascular system until the filter is positioned at an appropriate location relative to the treatment location, such as downstream of the treatment location.** The sizes of proximal stop 108 and distal stop 110 help to prevent catheter 100 from premature or unintentional contraction during the insertion process.

See Douk, Paragraphs 0030 and 0031 (emphasis added).

Applicant respectfully points out that were one to incorporate "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" of Claim 1 into the structure of Douk, Douk would no longer provide "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106 … Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**." Thus, any modifications/combinations would change the principle of operation of Douk for at least this reason.

As discussed above, one reason why such modified Douk technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Douk technology to provide "[f] wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically**

extend from the body portion under control of the control circuitry without requiring physical access by an individual" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Douk.

As has been shown above, any modification of Douk would require "substantial reconstruction and redesign of the elements shown in [...Douk] as well as a change in the basic principle under which the [...Douk] construction was designed to operate" in order to reach the recitations of Claim 1.[60] Accordingly, insofar as that any modification to Douk would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Douk.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Douk capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Douk will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Independent Claim 1 patentable and issue a Notice of Allowance of Applicant's Independent Claim 1 for at least the foregoing reasons.

(3) Modifications to Meet the Recitations of Independent Claim 1 Render Components Being Modified Unsatisfactory for their Intended Purposes; No Teaching to Modify/Combine Components as a Matter of Law.

Furthermore, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." With respect to this point, Applicant respectfully directs the

[60] This statement reflects Applicant's current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Douk's intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE
>
> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).
>
> As noted above, the USPTO has stated as follows:
>
> Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.
>
> Office Action, p. 6 (14 Oct 2009). [61]

[61] Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, but appears to have not addressed the express language of both Applicant's claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the

Applicant again points out that the USPTO has provided no evidence to modify/combine the cited technical materials to reach the recitations of Independent Claim 1. Even assuming, ***arguendo,*** that the USPTO had produced an as-yet-unknown objective teaching of how to modify/combine the structure of Labbe with the technology of Douk to create "wherein the plurality of retractable segments of the extensible finger are **configured while in vivo to controllably telescopically extend from the body portion under control of the control circuitry without requiring physical access by an individual**" (as set forth in Independent Claim 1) such a modification/combination would apparently render the technology of Labbe unsatisfactory for one or more of its intended purposes.

Labbe recites, "Referring now to the drawings, there is shown **an implantable dispenser 2 for use in a drug delivery system** where the dispenser is implanted into the body of a human being and is **operative to dispense into the body suitable quantities of a drug at intervals under control of a circuit within the dispenser** and as required under external control by means of a receiver/transmitter arrangement." *See Labbe*, Col. 2, Lines 53-60 (emphasis added). It is unclear, at best, how this purpose could be served in conjunction with "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106** … **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**" as recited by Douk. Thus, for at least this reason, the suggested modifications/combinations would render the technology of Labbe unsatisfactory for one or more of its intended purposes. There can thus be no teaching to modify/combine such references to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, and in light of the MPEP standards for patentability as set forth above, Applicant respectfully requests that the USPTO hold Applicant's Independent Claim 1 patentable and issue a Notice of Allowance of Independent Claim 1 for at least the reasons set forth herein.

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unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

6. Dependent Claims 2-34 and 66-71 Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-34 and 66-71[62] depend either directly or indirectly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-34 and 66-71 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that the USPTO hold Dependent Claims 2-34 and 66-71 patentable for at least the foregoing reasons, and issue a Notice of Allowability on same.

VI. CONCLUSION

Applicant may have during the course of prosecution cancelled and/or amended one or more claims. Applicant notes that any such cancellations and/or amendments will have transpired (i) prior to issuance and (ii) in the context of the rules that govern claim interpretation during prosecution before the United States Patent and Trademark Office (PTO). Applicant notes that the rules that govern claim interpretation during prosecution form a radically different context than the rules that govern claim interpretation subsequent to a patent issuing. Accordingly, Applicant respectfully submits that any cancellations and/or amendments during the course of prosecution should be held to be tangential to and/or unrelated to patentability in the event that such cancellations and/or amendments are viewed in a post-issuance context under post-issuance claim interpretation rules.

Insofar as that the Applicant may have during the course of prosecution cancelled/amended claims sufficient to obtain a Notice of Allowability of all claims pending, Applicant may not have during the course of prosecution explicitly addressed all rejections and/or statements in Office Actions. The fact that rejections and/or statements may not be

[62] In relation to these dependent claims, the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of its assertions regarding what the USPTO-cited material "discloses." Insofar as this alleged disclosure is not literally recited in such material, Applicant respectfully asserts that the Examiner must have relied on "personal knowledge" or taken improper "official notice" of one or more factors to reach each of these assertions. Applicant accordingly requests an appropriate affidavit or declaration in support of any of these rejections that are to be maintained, including any considerations purported to reflect what is "well known in the art." *See, e.g.*, 37 C.F.R. 1.104(d)(2).

explicitly addressed during the course of prosecution should NOT be taken as an admission of any sort, and Applicant hereby reserves any and all rights to contest such rejections and/or statements at a later time. Specifically, no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended (e.g., with respect to any facts of which the USPTO took Official Notice, and/or for which the USPTO has supplied no objective showing, Applicant hereby contests those facts and requests express documentary proof of such facts at such time at which such facts may become relevant). For example, although not expressly set forth during the course of prosecution, Applicant continues to assert all points of (e.g. caused by, resulting from, responsive to, etc.) any previous Office Action, and no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended. Specifically, insofar as that Applicant does not consider the cancelled/unamended claims to be unpatentable, Applicant hereby gives notice that it may intend to file and/or has filed a continuing application in order prosecute such cancelled/unamended claims.

With respect to any cancelled claims, such cancelled claims were and continue to be a part of the original and/or present patent application(s). Applicant hereby reserves all rights to present any cancelled claim or claims for examination at a later time in this or another application. Applicant hereby gives public notice that any cancelled claims are still to be considered as present in all related patent application(s) (e.g. the original and/or present patent application) for all appropriate purposes (e.g., written description and/or enablement). Applicant does NOT intend to dedicate the subject matter of any cancelled claims to the public.

Should this case go to appeal, Applicant reserves the right to submit argument, rebuttal evidence, or legal authority in the instance the Board of Patent Appeals and Interferences finds that the USPTO has met its burden in establishing a *prima facie* case of unpatentability of the various appealed claims. Applicant further reserves the right to submit argument, rebuttal evidence, or legal authority if new claim interpretations or definitional citations are raised on appeal. The fact that argument, rebuttal evidence, or legal authority may not have been explicitly discussed during the course of prosecution should NOT be taken as an admission or waiver of any sort, and Applicant hereby reserves any and all rights to discuss (e.g. make explicit, produce, or explain) such rebuttal evidence at a later time.

The USPTO is encouraged to contact the undersigned by telephone at 206-838-6400 to discuss the above and any other distinctions between the claims and the applied references, if

desired. Also, if the USPTO notes any informalities in the claims, it is encouraged to contact the undersigned to expediently correct such informalities.

Respectfully submitted,

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Encl: Replacement Formal Drawings
Extra claim fees